1614

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: TOVEY, Michael

Application No.: 09/243,030 Conf. No.: 1869

Filed: February 3, 1999

For: THERAPEUTIC APPLICATIONS OF HIGH DOSE INTERFERON

Art Unit: 1614

Examiner: J. Goldberg

Washington, D.C.

Atty.'s Docket: TOVEY=1A

Date: January 21, 2003

THE COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

Sir:

Transmitted herewith is a [ ] Amendment [X] RESPONSE in the above-identified application.

[ ] Small Entity Status: Applicant(s) claim small entity status. See 37 C.F.R. §1.27.

[XX] No additional fee is required.

[ ] The fee has been calculated as shown below:

	(Col. 1) CLAIMS REMAINING AFTER AMENDMENT		(Col. 2) HIGHEST NO. PREVIOUSLY PAID FOR	(Col. 3) PRESENT EXTRA EQUALS	SMALL ENTITY RATE	SMALL ENTITY ADDITIONAL FEE	OR	OTHER THAN SMALL ENTITY RATE	OTHER THAN SMALL ENTITY ADDITIONAL FEE
TOTAL	*	MINUS	** 30	10	x 9	$		x 18	$
INDEP.	*	MINUS	*** 3	0	x 42	$		x 84	$
FIRST PRESENTATION OF MULTIPLE DEP. CLAIM					+ 140	$		+ 280	$
					ADDITIONAL FEE TOTAL	$	OR	TOTAL	$

* If the entry in Col. 1 is less than the entry in Col. 2, write "0" in Col. 3.

** If the "Highest Number Previously Paid for" IN THIS SPACE is less than 20, write "20" in this space.

*** If the "Highest Number Previously Paid for" IN THIS SPACE is less than 3, write "3" in this space.

The "Highest Number Previously Paid For" (total or independent) is the highest number found from the equivalent box in Col. 1 of a prior amendment of the number of claims originally filed.

[XX] Conditional Petition for Extension of Time

If any extension of time for a response is required, applicant requests that this be considered a petition therefor.

[ ] It is hereby petitioned for an extension of time in accordance with 37 CFR 1.136(a). The appropriate fee required by 37 CFR 1.17 is calculated as shown below:

Small Entity		Other Than Small Entity	
Response Filed Within		Response Filed Within	
[ ] First	- $ 55.00	[ ] First	- $ 110.00
[ ] Second	- $ 200.00	[ ] Second	- $ 400.00
[ ] Third	- $ 460.00	[ ] Third	- $ 920.00
[ ] Fourth	- $ 720.00	[ ] Fourth	- $ 1440.00
Month After Time Period Set		Month After Time Period Set	

[ ] Less fees ($_____) already paid for ___ month(s) extension of time on _____.

[ ] Please charge my Deposit Account No. 02-4035 in the amount of $_____.

[ ] Credit Card Payment Form, PTO-2038, is attached, authorizing payment in the amount of $_____

[ ] A check in the amount of $_____ is attached (check no.).

[XX] The Commissioner is hereby authorized and requested to charge any additional fees which may be required in connection with this application or credit any overpayment to Deposit Account No. 02-4035. This authorization and request is not limited to payment of all fees associated with this communication, including any Extension of Time fee, not covered by check or specific authorization, but is also intended to include all fees for the presentation of extra claims under 37 CFR §1.16 and all patent processing fees under 37 CFR §1.17 throughout the prosecution of the case. This blanket authorization does not include patent issue fees under 37 CFR §1.18.

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant(s)

By: _____
Roger L. Browdy
Registration No. 25,618

Facsimile: (202) 737-3528
Telephone: (202) 628-5197

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

ATTY.'S DOCKET: TOVEY=1A

In re Application of:	)	Conf. No. 1869
Michael TOVEY	)	Art Unit: 1614
Appln. No.: 09/243,030	)	Examiner: J. Goldberg
Filed: February 3, 1999	)	Washington, D.C.
For: THERAPEUTIC APPLICATIONS OF HIGH DOSE INTERFERON	)	January 21, 2003

RESPONSE

Honorable Commissioner of Patents
Washington, D.C. 20231

Sir:

The present communication is responsive to the official action of October 8, 2002. Claims 22-51 presently appear in this case. No claims have been allowed. The official action October 18, 2002, has now been carefully studied. Reconsideration and allowance are hereby respectfully urged.

Briefly, claims 22-51 have been rejected under 35 U.S.C. 103(a) as being unpatentable over the Canadian patent 1,297,788 (Feinberg) taken with the Eby, III patent. The examiner states that Feinberg teaches the application of interferon at 5-75 million IU for treating the virus causing AIDS. The examiner states that Eby teaches the application of interferon by oral mucosa to treat other viral infections.

The examiner states that Feinberg does not teach the oral mucosa administration, but that one skilled in the art would find ample motivation from the prior art to employ the interferon by oral mucosa with the reasonable expectation that the interferon would be effective to combat the viral infection in the absence of a showing of oral mucosa versus injectable form for the high dosages disclosed. This rejection is respectfully traversed.

The examiner states that one skilled in the art would find ample motivation from Feinberg and Eby to treat HIV by the oromucosal administration of interferon in light of the disclosure of Eby. It is urged, however, that a careful reading of both references will show that the teachings of each are quite diverse and there would be no motivation for one of ordinary skill in the art to combine the two. In other words, one of ordinary skill in the art reading these two references would have no reasonable expectation that there would be any advantage in treating HIV with interferon by oromucosal administration as opposed to administration by injection as taught by Feinberg.

The primary reference is directed to the treatment of AIDS virus with recombinant human alpha interferon. At page 4, lines 2 to 3, it states that the interferon is "administered by injection e.g. subcutaneously". In the 6th

line from the bottom of the same page, it uses the term "parenterally" to describe the mode of administration. The second paragraph on page 6 states that the preferred mode of administering the interferon is by subcutaneous injection, because the patient can self-treat. Thus, this reference is directed to treating only a single type of virus by a very specific mode of administration.

The secondary reference, Eby, is also directed to treating a specific type of virus by a very specific mode of administration. Eby is directed to the treatment of "acute viral infections of the nose usually caused by rhinoviruses" (column 1, lines 52-53). Eby states, at column 3, lines 24-33:

> Since zinc gluconate works in the oral cavity but not in the nose, this inventor believes and teaches that all suitable common cold medicaments such as antiviral agents, antirhinoviral agents, interferon, interferon inducers, T-cell lymphocyte mitogens, decongestant, drying agents, astringents, antihistamines, antibradikinins, and all other pharmaceutical agents suitable for treating common colds will have efficacy, or greater efficacy, when applied to the oral mucosa than when applied to the inside of the nose, injected or swallowed.

Thus, the Eby disclosure is not directed to an improved mode of administration of interferon. It is only directed to an improved mode of administration of a common cold medicament,

of which interferon is only one of a long list of possible medicaments.

Eby also teaches the reason why it is desired to apply to the oral mucosa when treating a rhinovirus infection, where he states in the second paragraph of column 4:

> Application of antiviral agents including antirhinoviral agents to the oral mucosa through the incorporation of said antiviral agents within a slow release lozenge or other similar oral means presents a new method of adminisration that has the potential to inject said medicament into the lymphatic system or otherwise to circulate into the nasal tissue and the locus of infection. Although the means by which zinc ion are transported into nasal tissues in the original demonstration of this technique is not known but is suspected to involve diffusion, osmosis and electrophoresis and drainage by the lymphatic system, it is suggested that the same means of transport would also apply to other antiviral agents.

In the following paragraph he states that all methods directed at reducing the duration of common colds through means of administering antiviral agents by swallowing, injection or by administration to the nose have proven unsatisfactory.

The examiner has not explained why a patent directed to an improved means of administration for treating a rhinoviral infection using any medicament that has previously been used for treating the common cold, including interferon as an example, would provide motivation to use the same mode

of administration when administering interferon for the purpose of treating HIV. HIV is not an infection of the nose. It would not be expected that diffusion, osmosis and electrophoresis and draining by the lymphatic system to cause circulation into the nasal tissue and the locus of infection when one has a rhinovirus, would have any applicability whatsoever to the complex and refractory condition which is HIV. In this regard, the examiner's attention is respectfully directed to MPEP 2143.01 directed to suggestion or motivation to modify the references. The prior art itself must suggest the desirability of the claimed invention. Note particularly *Ex parte Levengood*, 28 USPQ 2d 1300, 1301 (Bd. Pat. App. Int. 1993) where it states:

> In order to establish a *prima facie* case of obviousness, it is necessary for the examiner to present evidence, preferably in the form of teaching, suggestion, incentive or inference in the applied prior art, or in the form of generally available knowledge, that one having ordinary skill in the art would have been led to combine the relevant teachings of the applied references in the proposed manner to arrive at the claimed invention. [emphasis added]

Here, there is no suggestion whatsoever why one of ordinary skill in the art would consider combining these references in the manner suggested by the examiner. It should be noted that the examiner erred, in stating "the Ely III [sic] patent teaches the application of interferon by oral

mucosa to treat other viral infections." This sentence would more accurately state that it teaches the application of interferon by oral mucosa to treat one specific viral infection, i.e., rhinovirus. It has no teaching whatsoever about any other viral infection. There is nothing in Eby that would suggest that the mode of administration therein would be applicable to any other viral infection. And, certainly, there is nothing to suggest that there is anything therein of general applicability to interferons in particular, since inteferons are only listed as one of a long list of possible common cold medicaments which may be administered in this manner to treat the common cold.

For all of these reasons, reconsideration and withdrawal of this rejection, and passage of all the claims now present in the claims to issue are earnestly solicited.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant(s)

By _____
Roger L. Browdy
Registration No. 25,618

RLB:ma
Telephone No.: (202) 628-5197
Facsimile No.: (202) 737-3528
G:\BN\P\phaq\Tovey1A\Pto\Response 21Jan03.doc